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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|-------------|------------------------------|---------------------|------------------|
| 10/009,579 | 03/22/2002 | Lou Franciscus M. H. De Leij | Rijk-15(P52075US00 | 1723 |
| 7265 | 7590 | 09/07/2004 | EXAMINER | |
| MICHAELSON AND WALLACE | | | QIAN, CELINE X | |
| PARKWAY 109 OFFICE CENTER | | | ART UNIT | PAPER NUMBER |
| 328 NEWMAN SPRINGS RD | | | 1636 | |
| P O BOX 8489 | | | | |
| RED BANK, NJ 07701 | | | | |
| DATE MAILED: 09/07/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|---------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/009,579 | DE LEI ET AL. | |
| | Examiner | Art Unit | |
| | Celine X Qian | 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 June 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Claims 1-18 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 6/1/04 is acknowledged. The traversal is on the ground(s) that the special technical feature of the claimed inventions is not disclosed in the prior art Baptist et al. Applicants argue that the tumor specific promoter of Baptist et al. is not a carcinoma selective promoter. As such, the special technical feature is novel in view of the cited prior art. Furthermore, Applicants argue that the novelty of the promoter is irrelevant for distinguishing the noted groups. Lastly, Applicants argue that the instant application complies the requirement of unity of invention during the PCT stage by the International Preliminary Examining Authority and urges the Examiner to follow the opinion of the IPEA to examine the entire application.

Applicants' arguments have been fully considered and deemed partially persuasive. The Examiner agrees that the cited reference Baptist et al. do not disclose a carcinoma selective promoter the invention of Group I, thus not support the lack of unity not requirement. However, Applicants are reminded that PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. As such, the novelty of the promoter, which is the special technical feature of Group I, is relevant in deciding whether the groups share a special technical feature. In response to Applicant's argument regarding opinion of the IPEA, it is noted that 37 CFR 1.499 states, "if the examiner finds that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the

claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the examiner.” Therefore, the lack of unity requirement may be made at national stage even the IPEA did not make such requirement during PCT examination. Nevertheless, in view of the improper application of the prior art in the previous office action, and upon further reviewing of the claims, the claimed inventions are re-grouped as following. The reasons for lack of unity are also given below.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, 14, drawn to drawn to a nucleic acid comprising a tissue specific promoter or a fragment of that promoter, that selectively expresses carcinoma cells, a vector comprising said nucleic acid, a host cell comprising said nucleic acid and a medicament comprising said nucleic acid.

Group II, claim(s) 11, drawn to drawn to an experimental animal comprising a cell which comprises a nucleic acid that comprises a tissue specific promoter that selectively expresses carcinoma cells.

Group III, claims 12, 13 and 15, drawn to a method for the treatment of cancer comprising administering to a patient a nucleic acid comprises a tissue specific promoter that selectively expresses carcinoma cells.

Group IV, claims 16-18, drawn to a method for evaluating a possible treatment of disease comprising testing such treatment on a host cell which comprises the nucleic acid that comprises a tissue specific promoter that selectively expresses carcinoma cells.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as

Groups I-VI do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The “special technical feature” of Group I is a tissue specific promoter or a fragment of that promoter, that is essentially carcinoma selective, which is shown by Chen et al., (J. Clin. Invest. 1996, Vol.98, no. 11, pages 2539-2548), who teach a DF3/MUC1 carcinoma selective promoter (see abstract), to lack novelty or inventive step over the disclosed tumor specific promoter, and does not make a contribution over the prior art. As such, this technical feature cannot link the invention as a whole to form a single general inventive concept under PCT Rule 13.1.

The invention of the remaining groups each has a unique technical feature not shared by the other groups. The special technical feature of Group II is an animal comprising a cell that comprises a tumor specific promoter, which is not shared by the remaining groups. The special technical feature of Group III is use of the tumor specific promoter in treating cancer. The special technical feature of Group IV is a method for evaluating a possible treatment by using a cell comprising a tumor specific promoter, which is not shared by the remaining groups. Therefore, the unity of invention does not exist between the claims of Groups I-IV.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

